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DAVID W. HIGHET, ESQ.
BECTON, DICKINSON AND COMPANY
1 BECTON DRIVE, MC 089
FRANKLIN LAKES, NJ 07417

EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/992,124	CAMPBELL ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2005 and 28 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41,44-46 and 48-52* is/are pending in the application.

4a) Of the above claim(s) *3,22-29,34,38-40,45 and 46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-17,19-21,30-33,35-37,41,44 and 48-52* is/are rejected.

7)☒ Claim(s) *18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Applicant's election of the species (d) xkxxx and the sequence SEQ ID NO:34 in the reply filed on September 20, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 3, 22-29, 34, 38-40, 45, and 46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected sequence. Election was made **without** traverse in the reply filed on September 20, 2004.

2. The Sequence Listing filed February 2, 2005 is approved.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 30-32 and 41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-53 of copending Application No. 10/259,816. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '816 application claims the peptides KKKK, DDEEK, KLMSY, and FFFKK, which anticipate the instant claimed peptides. The claims of the '816 application recite the use of the peptides as a coating for biomedical devices. The claimed peptides, either alone or in combination with the other claimed peptides of the '816 application,

also constitute a peptide library. In view of the similarity in structure between the peptides claimed in the '816 application and the instant claimed peptides, inherently the peptides claimed in the '816 application will enhance cell growth and/or secretion in a cell culture system, will promote adherence of anchorage-dependent cells on a surface, and will increase oxygen consumption of cells to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptides claimed in the '816 application and the instant claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than those of the '816 application. With respect to, e.g., claim 32, an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated or obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1, 2, 5-17, 19-21, 33, 36, and 37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of copending Application No. 10/641,286. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '286 application anticipate the instant claims. See especially SEQ ID NOS: 1-3, 5-13, 15, and 16 of the '286 application. Note that the CAR material can be a polysaccharide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1, 2, 5-17, 19-21, 33, 36, and 37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-66 of

copending Application No. 10/670,771. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '771 application anticipate the instant claims. See especially SEQ ID NOS: 1-3, 5-13, 15, and 16 of the '771 application. Note that the CAR material can be a polysaccharide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1, 2, 5-7, 10-12, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,759,510. The '510 patent claims SEQ ID NOS:25, 30, 34, 40, 53-55, 58, 62, 70-72, 79-81, and 86-88, which have the same structure as is recited in the instant claims. In view of the similarity in structure between the peptides claimed in the '510 patent and the instant claimed peptides, inherently the peptides claimed in the '510 patent will enhance cell growth and/or secretion in a cell culture system, will promote adherence of anchorage-dependent cells on a surface, and will increase oxygen consumption of cells to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptides claimed in the '510 patent and the instant claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than those of the '510 patent. With respect to, e.g., claims 5-7, 10, and 19, an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated or obvious. In addition, the '510 patent teaches the use of the peptides in free form in cell cultures. See, e.g., column 8, lines 16-31, and column 10, lines 10-35.

9. Claims 1, 2, 4-7, 19, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyazaki et al (U.S. Patent No. 5,411,956). Miyazaki et al teach the peptide α-(L-lysine)$_5$ (see Table 6), which has the same structure as is recited in instant claims 1, 49, and 50. The peptide is present in a distilled water solution, which inherently requires a container to contain the solution. In view of the similarity in structure between the peptide of Miyazaki et al and the instant claimed peptides, inherently the peptide of Miyazaki et al will enhance cell growth and/or

secretion in a cell culture system, will promote adherence of anchorage-dependent cells on a surface, and will increase oxygen consumption of cells to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptide of Miyazaki et al and the instant claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than that of Miyazaki et al. With respect to, e.g., claims 5-7 and 19, an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated or obvious.

10. Claims 1, 2, 5-9, 13, 19-21, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by the Ramachandran et al article (J. Org. Chem., Vol. 28, pages 173-177). The Ramachandran et al article teaches the pentapeptide VKVYP. The pentapeptide is dissolved in water, and then lyophilized. See, e.g., page 177, column 1, fourth full paragraph. The pentapeptide dissolved in water corresponds to Applicants' peptide in free form, and the lyophilized pentapeptide corresponds to Applicants' peptide noncovalently immobilized to a cell culture surface, i.e. in the form of a dried film. In view of the similarity in structure between the pentapeptide of the Ramachandran et al article and the instant claimed peptides, inherently the pentapeptide of the Ramachandran et al article will enhance cell growth and/or secretion in a cell culture system, and will promote adherence of anchorage-dependent cells on a surface to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the pentapeptide of the Ramachandran et al article and the instant claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than that of the Ramachandran et al article. With respect to, e.g., claims 5-7 and 19, an

intended use limitation does not impart patentability to product claims where the product is otherwise anticipated or obvious.

11. Claims 30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by the Yaron et al article (Biopolymers, Vol. 11, pages 607-621). The Yaron et al article teaches the peptides KK, KKK, and KKKK. See, e.g., the Abstract and Figures 1 and 5. In view of the similarity in structure between the peptides of the Yaron et al article and the instant claimed peptides (see Applicants' SEQ ID NOS:66-68), inherently the peptides of the Yaron et al article will enhance cell secretion to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptides of the Yaron et al article and the instant claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than those of the Yaron et al article. With respect to claim 32, an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated or obvious.

12. Claims 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by the Grahl-Nielsen et al article (Biochemistry, Vol. 8, pages 187-192). The Grahl-Nielsen et al article teaches the peptides KK, KKK, and KKKK. Solutions of the peptides are lyophilized. See, e.g., the Abstract; Figure 4; and page 189, column 1, third full paragraph. The lyophilized peptides correspond to Applicants' peptide attached or non-specifically adsorbed to a surface, e.g., in the form of a dried film. In view of the similarity in structure between the peptides of the Grahl-Nielsen et al article and the instant claimed peptides (see Applicants' SEQ ID NOS:66-68), inherently the peptides of the Grahl-Nielsen et al article will enhance cell secretion to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between

the peptides of the Grahl-Nielsen et al article and the instant claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than those of the Grahl-Nielsen et al article. With respect to claim 32, an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated or obvious.

13. Claims 1, 2, 5-7, 19, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by the Zahn et al article (Ann. Chem., Vol. 636, pages 117-131). The Zahn et al article teaches the pentapeptide GKGEG. See, e.g., page 118, last line of the synthesis scheme. The pentapeptide corresponds to Applicants' peptide in free form. In view of the similarity in structure between the pentapeptide of the Zahn et al article and the instant claimed peptides, inherently the pentapeptide of the Zahn et al article will enhance cell growth and/or secretion in a cell culture system, and will promote adherence of anchorage-dependent cells on a surface to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the pentapeptide of the Zahn et al article and the instant claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than that of the Zahn et al article. With respect to, e.g., claims 5-7 and 19, an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated or obvious.

14. Claims 30, 32, 44, 48-50, and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by the Payne article (Biochemical Journal, Vol. 123, pages 255-60). The Payne article teaches culturing E. coli in the presence of triornithine, dilysine, and trilysine. See, e.g., page 255, column 2, second paragraph; the paragraph bridging pages 255 and 256; page 257, first full paragraph; Figure 4. The peptides of the Payne article correspond to Applicants' SEQ ID NOS:67-69. In view of the similarity in structure and method steps between the peptides of the

Payne et al article and the instant claimed peptides and methods, inherently the peptides of the Payne et al article will enhance secretion in a cell culture system to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptides and methods of the Payne et al article and the instant claimed peptides and methods to shift the burden to Applicants to provide evidence that the claimed peptides and methods are unobviously different than those of the Payne et al article.

15. Claims 1, 2, 4-7, 19, 30, 32, and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Calenoff et al (U.S. Patent Application Publication 2005/0048588). Calenoff et al teach the pentapeptide HKNQT. See, e.g., Table 3 at page 7. In view of the similarity in structure between the peptide of Calenoff et al and the instant claimed peptides, inherently the peptide of Calenoff et al will enhance cell growth and/or secretion in a cell culture system and will promote adherence of anchorage-dependent cells on a surface to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptide of Calenoff et al and the instant claimed peptides and methods to shift the burden to Applicants to provide evidence that the claimed peptides and methods are unobviously different than that of Calenoff et al. With respect to claims 5-7, 19, and 41, intended use limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art.

16. Claims 1, 2, 5-7, 20, and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Katinger et al (U.S. Patent Application Publication 2004/0072341). Katinger et al teach the pentapeptide Ala-Ala-Gly-Gly-Lys, to be used in cell culture media to improve growth rate and secretion of proteins. See, e.g., the Abstract and paragraphs [0008] and [0022]. With respect to

claims 5-7, intended use limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art.

17. Claims 1, 2, 5-7, 10-12, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 99/51254. The WO Patent Application '254 teaches culturing neuronal cells in the presence of the peptide IKEYF. See Figure 1. In view of the similarity in structure between the peptide of the WO Patent Application '254 and Applicants' claimed peptide, inherently the peptide of the WO Patent Application '254 will enhance cell growth and/or secretion, will promote adherence of anchorage-dependent cells on a surface, will increase oxygen consumption of the cells, and will increase the growth of the cells in vivo, to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the peptide of the WO Patent Application '254 and the instant claimed peptides and methods to shift the burden to Applicants to provide evidence that the claimed peptides and methods are unobviously different than that of the WO Patent Application '254. With respect to claims 5-7, intended use limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art.

18. Claims 1, 2, 5-7, 10-12, and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Green et al (U.S. Patent No. 6,100,380). Green et al teach the pentapeptides Thr-Ala-Glu-Glu-Lys (i.e. HM897), Thr-Pro-Glu-Glu-Lys, and Thr-Pro-Gln-Gln-Lys. HM897 is used in in vitro cell cultures of T- and B-lymphocytes. See, e.g., column 10, lines 7-8; Example 4; and claim 5. In view of the similarity in structure between the peptides of Green et al and Applicants' claimed peptides, inherently the peptides of Green et al will enhance cell growth and/or secretion, will promote adherence of anchorage-dependent cells on a surface, will increase

oxygen consumption of the cells, and will increase the growth of the cells in vivo, to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the peptides of Green et al and the instant claimed peptides and methods to shift the burden to Applicants to provide evidence that the claimed peptides and methods are unobviously different than those of Green et al. With respect to claims 5-7, intended use limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art.

19. Claims 1, 2, 5-7, 10-12, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 00/15188. (The examiner relies upon U.S. Patent No. 6,620,419 as a translation of the WO Patent Application '188. All citations in this rejection will be to the translation.) The WO Patent Application '188 teaches culturing skin cells and fibroblasts in the presence of the peptide N-palmitoyl-Sar-Thr-Thr-Lys-Ser. The presence of the peptide results in an increase in collagen, glycosaminoglycan, and protein synthesis. See Examples 4 and 5. In view of the similarity in structure and activity of the final pentapeptide product, the Sar which is present in the pentapeptide of the WO Patent Application '188 is deemed to be a derivative of the amino acids named in instant claim 1. In view of the similarity in structure and method of use between the peptide of the WO Patent Application '188 and Applicants' claimed peptide, inherently the peptide of the WO Patent Application '188 will enhance cell growth and/or secretion, will promote adherence of anchorage-dependent cells on a surface, will increase oxygen consumption of the cells, and will increase the growth of the cells in vivo, to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the peptide of the WO Patent Application '188 and the instant claimed peptides and methods to shift the burden to Applicants to provide evidence that the claimed peptides and methods are

unobviously different than those of the WO Patent Application '188. With respect to claims 5-7, intended use limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art.

20. Claims 1, 2, 4-9, 13-16, 19, 30-33, 35, and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Dean et al (U.S. Patent Application Publication 2003/0175745). Dean et al teach a pentapeptide FFFKK (corresponding to Applicants' SEQ ID NO:47) and a tetrapeptide KKKK (corresponding to Applicants' SEQ ID NO:66). Dean et al further teach an article such as a biomedical device, a film, or microparticles, comprising a solid surface which is coated with a cell adhesion resistant material such as hyaluronic acid or alginic acid (which are polysaccharides) and which is further impregnated or coated with the peptides discussed above. The peptides can also be conjugated to a carrier such as immunoglobulins and polysaccharides. See, e.g., paragraphs [0040] and [0175], and claims 1, 16, 19, 20, 24, 26, and 27. In view of the similarity in structure between the peptides of Dean et al and Applicants' claimed peptides, the peptides of Dean et al will inherently enhance cell growth and/or secretion and promote adherence of at least one anchorage-dependent cell for at least one cell to the same extent claimed by Applicants. Note that Applicants' claims do not specify which cell or cells must have their growth or secretion enhanced or their adherence promoted. Sufficient evidence of similarity is deemed to be present between the peptides of Dean et al and Applicants' claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than those of Dean et al. With respect to claims 5-7, 19, 32, 33, and 41, note that an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated by the prior art.

21. Claims 1, 2, 5-7, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by the Katayama et al article (J. Biol. Chem., Vol. 268, pages 9941-9944). The Katayama et al article teaches culturing human lung fibroblasts in the presence of a medium comprising Lys-Thr-Thr-Lys-Ser. See, e.g., the Abstract and Figure 1. In view of the similarity in structure between the peptide of Katayama et al and Applicants' claimed peptides, the peptide of Katayama et al will inherently enhance cell growth and/or secretion and promote adherence of at least one anchorage-dependent cell for at least one cell to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptide of Katayama et al and Applicants' claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than that of Katayama et al. With respect to claims 5-7, note that an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated by the prior art.

22. Claims 1, 2, 5-7, 10-12, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by the Rastogi et al article (FEBS Lett., Vol. 317, No. 1-2, pages 93-95). The Rastogi et al article teaches culturing NK cells and lymphocytes in the presence of the pentapeptide Lys-Lys-Glu-Val-Tyr. See, e.g., sections 2.2 and 2.3, and Table I. In view of the similarity in structure and method of use between the peptide of the Rastogi et al article and Applicants' claimed peptide, inherently the peptide of the Rastogi et al article will enhance cell growth and/or secretion, will promote adherence of anchorage-dependent cells on a surface, will increase oxygen consumption of the cells, and will increase the growth of the cells in vivo, to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the peptide of the Rastogi et al article and the instant claimed peptides and methods to shift the

burden to Applicants to provide evidence that the claimed peptides and methods are unobviously different than that of the Rastogi et al article. With respect to claims 5-7, intended use limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art.

23. Claims 30, 32, 41, 44, 48-50, and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by the Grahl-Nielsen et al article (In Vitro, Vol. 9, pages 414-420). The Grahl-Nielsen et al article teaches culturing mammalian cells in the presence of dilysine, tetralysine, heptalysine, and decalysine, thereby increasing the growth rate of the cells. See, e.g., Figure 2. Dilysine and tetralysine correspond to Applicants' SEQ ID NOS:66 and 68. In view of the similarity in structure and method steps between the peptides and culturing method of the Grahl-Nielsen et al article and Applicants' claimed peptides and culturing methods, inherently the peptides and culturing method of the Grahl-Nielsen et al article will enhance cell secretion to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptides and method steps of the Grahl-Nielsen et al article and Applicants' claimed peptides and methods to shift the burden to Applicants to provide evidence that the claimed peptides and methods are unobviously different than those of the Grahl-Nielsen et al article.

24. Claim 51 is rejected under 35 U.S.C. 103(a) as being obvious over the Grahl-Nielsen et al article (In Vitro, Vol. 9, pages 414-420). Application of the Grahl-Nielsen et al article is the same as in the above rejection of claims 30, 32, 41, 44, 48-50, and 52. The Grahl-Nielsen et al article does not teach Applicants' claimed peptide concentrations (compare the peptide concentrations disclosed at, e.g., Figure 2 and the paragraph bridging pages 416 and 417). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was

made to determine all operable and optimal peptide concentrations for the culture methods of the Grahl-Nielsen et al article because concentration is an art-recognized result-effective variable which is routinely determined and optimized in the cell culture arts, and because Figure 2 of the Grahl-Nielsen et al article indicates that increasing the peptide concentration results in an increase in cell growth rate.

25. Claims 1, 2, 5-13, 19-21, 33, 36, and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Uhrich et al (U.S. Patent Application Publication 2003/0104614). Uhrich et al teach a pentapeptide IKVAV which is absorbed onto a surface and used for the culture of neurites. See, e.g., paragraph [0051] and claims 1-3 and 18. In view of the similarity in structure and method of use between the peptide of Uhrich et al and Applicants' claimed peptides, the peptide of Uhrich et al will inherently enhance cell growth and/or secretion, promote adherence of at least one anchorage-dependent cell, and increase oxygen consumption for at least one cell to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptides of Dean et al and Applicants' claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than those of Dean et al. With respect to claims 5-7, note that an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated by the prior art.

26. Claims 1, 2, 5-7, 10-13, 16, 17, 19-21, 33, 36, and 37 are rejected under 35 U.S.C. 103(a) as being obvious over Bryhan et al (U.S. Patent No. 5,563,215) in view of Hubbell et al (U.S. Patent No. 5,330,911) or Zamora (U.S. Patent No. 5,738,838). Bryhan et al teach a cell culture medium in which a dialdehyde starch is coated onto a surface, and a cell adhesive peptide is coupled to the dialdehyde starch coating. See, e.g., the Abstract; column 5, lines 30-40; and

claim 1. Bryhan et al do not teach a cell adhesive peptide having the pentameric structure required by Applicants' claims. Hubbell et al teach attaching the pentapeptide IKVAV to a cell culture surface in order to promote cell growth. See, e.g., the Abstract; column 6, lines 45-47; and column 9, lines 18-20. Zamora teaches IKVAV to be an adhesive peptide for mast cells and neurites. See, e.g., column 3, line 23 - column 4, line 7. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use the IKVAV peptide of Hubbell et al and Zamora as the cell adhesive peptide required by Bryhan et al, because Bryhan et al are not limited to any particular cell adhesive peptide, because Hubbell et al and Zamora teach IKVAV to have the cell adhesive properties required by Bryhan et al, because use of the IKVAV of Hubbell et al and Zamora as the cell adhesive peptide of Bryhan et al would permit mast cells and neurites to be cultured with the cell culture medium of Bryhan et al, and because substitution of a known species for a known genus is prima facie obvious. With respect to instant claims 5-7, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal cell adhesive peptide concentrations for the cell culture medium of Bryhan et al as modified above by Hubbell et al or Zamora because concentration is an art-recognized result-effective variable which is routinely determined and optimized in the cell culturing arts.

27. Applicant's arguments filed February 2, 2005 and February 28, 2005 have been fully considered but they are not persuasive.

The anticipation rejection over U.S. Patent No. 6,759,510 is maintained. Applicants cite to MPEP 806.04(i) and argue that the section requires withdrawal of the anticipation rejection. However, this section of the MPEP, and Brathwaite, are limited to the issue of obviousness-type

double patenting. It is permissible to make a prior art rejection of generic claims over species claims with an earlier effective filing date, and a terminal disclaimer is ineffective to overcome this type of prior art rejection. See, e.g., MPEP 804, Chart II-B; MPEP 804(III); and MPEP 2131.02.

The rejection of certain of Applicants' claims over Miyazaki et al (U.S. Patent No. 5,411,956) is maintained. Applicants contend that Miyazaki et al do not teach or suggest a cell culture system. The examiner agrees that Miyazaki et al do not intend to use their α-(L-lysine)$_5$ to culture cells; however, whether Miyazaki et al teach a product which anticipates Applicants' system claims is a different issue. Firstly, it has to be determined what components are required by Applicants' "cell culture system" limitation (keeping in mind that a specific intent to culture cells is not a required component of a product claim). Independent claim 1 positively recites only one component, a pentameric peptide which must have a specified amino acid sequence and which must be free or noncovalently immobilized to a cell culture surface. The claim does not positively require that any other component be present, e.g., does not require the presence of cells and does not require the presence of a cell culture medium. Note that cells and media are only mentioned in dependent claims 10 and 19. It is possible that the claim requires a cell culture surface to be present, although a cell culture surface is only mentioned in conjunction with a noncovalently immobilized peptide. If there is some unrecited component which is required by Applicants' cell culture system claims and which is lacking in the prior art, Applicants should specifically identify that unrecited component, so that a more accurate determination of patentability can be made. Secondly, insofar as the required components of Applicants' claimed cell culture system have been identified, these components are taught by

Miyazaki et al. Miyazaki et al teach the peptide in a distilled water solution which inherently must require the presence of a container. (Any container in which an aqueous peptide solution can be stored can function as a cell culture surface.) Accordingly, prima facie anticipation is deemed to be established. With respect to claim 41, the only component required by the claim is a peptide, which is taught by Miyazaki et al. To characterize the peptide as a "cell culture substrate" is merely to recite an inherent property or an intended use of the peptide, and does not require that any other component be present or combined with the claimed peptide.

The Payne et al article (Biochemical Journal, Vol. 123, pages 255-60) is not applied against instant claim 51. Note that the triornithine, dilysine, and trilysine concentrations taught by the Payne article are significantly less than those recited in Applicants' claim. Further, because culturing in the presence of the peptides is not reported by the Payne et al article to achieve patentably useful results, there is not deemed to be any motivation in the art to modify or optimize the peptide concentrations in the culture method of the Payne article.

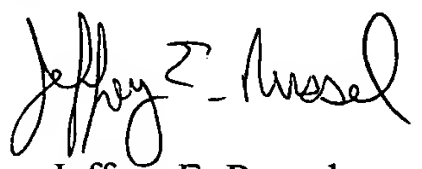
28. Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art of record does not teach or suggest pentapeptides of the structures recited in instant claim 1 covalently linked to at least one of bFGF, GCSF, an ILGF-1, or VEGF. Further, instant claims 8-18, 31, 33, 35, 44, and 48, limited to Applicants' elected SEQ ID NO:34, would also be novel and unobvious over the prior art of record, and particularly over Calenoff et al (U.S. Patent Application Publication 2005/0048588) which has been applied above.

29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
May 3, 2005